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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FISHER, ABIGAIL L	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,782	PLAT ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,8,14,15,17,20,21,24,27,30,33 and 53-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,8,14,15,17,20,21,24,27,30,33 and 53-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on June 30 2009 and December 18 2009 is acknowledged. Claims 3-4, 6-7, 9-13, 16, 18-19, 22-23, 25- 26, 28-29, 31-32 ad 34-52 were/stand cancelled. Claims 53-57 were added. Claims 1-2, 5, 8, 14-15, 17, 20-21, 24, 27, 30, 33 and 53-57 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/2/09 was considered by the examiner.

Response to Amendment

The Declaration under 37 CFR 1.132 filed December 18 2009 is sufficient to overcome the following rejections:

The rejection of claims 1, 3-8, 18 and 42-44 under 35 U.S.C. 102(b) as being anticipated by Buchholz et al. (US Patent No. 6514973, cited on PTO Form 1449).

The rejection of claims 1, 3-5, 18 and 42-44 under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 01/84961).

The rejection of claims 1, 3-5, 18 and 42-44 under 35 U.S.C. 102(b) as being anticipated by Hensley et al. (WO 01/82902).

The rejection of claims 2, 21-22, 24-25, 27-28, 30 and 33 under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. in view of Haynes et al. (US Patent No. 5015483).

The rejection of claims 2, 21-22, 24-25, 27-28, 30 and 33 under 35 U.S.C. 103(a) as being unpatentable over Hensley et al. in view of Haynes et al. (US Patent No. 5015483).

The rejection of claims 2, 9-19, 21-22, 24-25, 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al.

New Objections Necessitated by the Amendments filed December 18 2009

Claim Objections

Claim 21 is objected to because of the following informalities: the article "a" before phosphatidylserine in line 1 should be "the". Appropriate correction is required.

Claim 24 is objected to because of the following informalities: the article "a" before phosphatidylserine in line 1 should be "the". Appropriate correction is required.

Claim 27 is objected to because of the following informalities: the article "a" before phosphatidylserine in line 1 should be "the". Appropriate correction is required.

New Rejections Necessitated by the Amendments filed December 18 2009

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5, 8, 14-15, 17, 20-21, 24, 27, 30, 33 and 53-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These are new matter rejections.

Claim 1 introduce new matter. Specifically, the claim recites the limitation: "predominantly in the form of its salt with a divalent ion". There is no support in the specification for the limitation that the PS is **predominately** in the form of a salt with a divalent ion. The limitation of: "predominately in the form of a salt with a divalent" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification (specifically the section pointed to by applicants) indicate that the PS is in the form of a salt, preferably a calcium salt (which is a divalent metal). However, there is no guidance in the specification to select a form of PS wherein only a portion of the PS is in the form of a salt with a divalent ion. While other salts are taught, the specification makes it clear that the PS is in the form of a salt such as sodium,

calcium, magnesium but mixtures of salts or mixtures of salt form and free base form are not taught nor contemplated. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5, 8, 14-15, 17, 20-21, 24, 27, 30, 33 and 53-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a stability of "less than about 1 to about 5%". Less than provides a static point and about provides a dynamic point and cannot be used to modify one another. Therefore, the scope of the claimed range is indefinite. Furthermore, the claim is indefinite because the use of less than and a range is confusing. It is unclear what is the upper limit being claimed is it less than 1 or less than 5?

The term "predominately" in claim 1 is a relative term which renders the claim indefinite. The term "predominately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "predominately" indicates a certain range is acceptable. However, the specification

does not discuss nor contemplate what is the minimum or maximum range for "predominately in the form of its salt with a divalent ion".

Claims 55-57 as currently written are vague and indefinite. The claims recite nutritional carbohydrates. However, neither the instant claims nor the instant specification indicates what these nutritional carbohydrates are. Furthermore, no guidance is given as to differentiate nutritional carbohydrates over other types of carbohydrates. The resulting claim does not clearly set forth the metes and bounds of the patent protection desired for nutritional carbohydrates.

Claims 2, 5, 8, 14-15, 17, 20-21, 24, 27, 30, 33 and 53-54 are included in the rejection as they depend on a rejected base claim.

New Rejections Necessitated by the Amendments filed December 18 2009

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 5, 8, 14-15, 17, 20-21, 24, 27, 30, 33 and 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFerra et al. (EP 922707) in view of Jorissen et al. (Nutritional Neuroscience, 2002).

Applicant Claims

The instant application claims a composition comprising a phosphatidylserine (PS) composition of matter comprising about 1 to about 99% (w/w) PS and an oil base wherein said PS is predominantly in the form of its salt with a divalent ion and is dispersed in said oil base, said composition exhibits a stability of less than about 1 to about 5% decomposition of the PS after a storage period of at least 6 months.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

DeFerra et al. is directed to a process for the purification of phosphatidylserine. DeFerra et al. teach a process for the purification of phosphatidylserines of formula I. It is taught that the importance of compounds of formula I is various particularly in the preparation of pharmaceutical composition for the therapy of involutive cerebral syndromes such as vascular pathologies on atheroschlerotic base and/or senile decline; for the preparation of liposomial formulations and dietetic compositions (paragraph 0003). The invention increases the purity of phosphatidylserine obtained from Epikuron 200. The further purified PS can be obtained by crystallization in the form of the calcium salt (paragraph 0008). Examples 1-3 exemplify preparing a purified phosphatidylserine as the calcium salt from various lecithin sources.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

While DeFerra et al. teach that phosphatidyl serine are important in the preparation of pharmaceutical composition for the therapy of involutive cerebral syndromes including those associated with senile decline, DeFerra et al. do not explicitly teach incorporating the phosphatidyl serine in a pharmaceutical composition. However, this deficiency is cured by Jorissen et al.

Jorissen et al. is directed to the safety of soy-derived phosphatidylserine in elderly people. It is taught that phosphatidylserine is claimed to improve memory performance in subjects suffering from age-associated memory impairment or Alzheimer's disease (page 337, introduction, first sentence). The study was designed to investigate the safety of two dosage of soy-phosphatidyl serine in elderly. The phosphatidylserine was administered as a powder in combination with

phosphatidylcholine, phosphatidyl-ethanolamine, phosphatidylinositol, phosphatidic acid and polyunsaturated fatty acid. The phospholipids mixture is encapsulated in a soft gelatin capsule in an amount equivalent to 50 to 100 mg of the mixture. The mixture is diluted with medium chain triglycerides to fill the rest of the capsule. Two capsules are taken three times daily. The ratio of the phospholipids mixture is as follows: 40% phosphatidyl serine, 9% phosphatidyl choline, 9% phosphatidyl ethanolamine, 5% phosphatidyl inositol, 5% phosphatidic acid and 28% polyunsaturated fatty acids (page 338, treatment). The supplements were shown to be safe (page 342, last paragraph).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of DeFerra et al. and Jorissen et al. and utilize the purified phosphatidylserine in the pharmaceutical composition of Jorissen et al. One of ordinary skill in the art would have been motivated to utilize the phosphatidylserine of DeFerra et al. in the pharmaceutical composition of Jorissen et al. as DeFerra et al. teach that the phosphatidyl serine is important in the preparation of pharmaceutical compositions. Therefore, it would have been obvious to utilize purified phosphatidyl serine in known phosphatidyl serine pharmaceutical compositions.

Regarding the claimed storage stability, DeFerra et al. is silent. However, DeFerra et al. teach utilizing the instantly claimed divalent salt of phosphatidyl serine. Since known pharmaceutical preparations utilize medium chain triglycerides for diluting phosphatidyl serine, their use is obvious. Therefore, based on the teaching of DeFerra et al. that the phosphatidyl serine utilized is the divalent salt and is a purer form of

phosphatidylserine, there is a reasonable expectation that the storage stability would be the same as instantly claimed. Because the PTO has no means to conduct analytical experiments and based on the substantially similar product components, the burden of proof is shifted to the Applicant to show that the functional limitation is not possessed by the prior art.

Regarding claim 21, since the soft gel capsules would be consumed by patients, the soft gel capsule encapsulating the phosphatidyl serine would read on a food article.

Regarding the claimed methods, DeFerra et al. teach that phosphatidyl serine is utilized in pharmaceutical composition for therapy of cerebral syndromes including senile decline and Jorissen et al. teach that phosphatidylserine is claimed to improve memory performance in Alzheimer's disease. Therefore, it would have been obvious to utilize the phosphatidyl serine in a method of enhancing cognitive performance and memory loss in people.

Regarding claims 2 and 55-57, the instant claim language recites and/or sterol or sterol esters. Therefore, one interpretation of the claims is that the sterols do not have to be present. The claims are rejected over this interpretation. Claims 55-57 recite an additional biofunctional ingredient. A biofunctional agent is listed is poly-unsaturated fatty acids which is recited as a component of the pharmaceutical composition of Jorissen et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-2, 5, 8, 14-15, 17, 20-21, 24, 27 and 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFerra et al. (EP 922707) in view of Douglas Laboratories (1999).

Applicant Claims

The instant application claims a composition comprising a phosphatidylserine (PS) composition of matter comprising about 1 to about 99% (w/w) PS and an oil base wherein said PS is predominantly in the form of its salt with a divalent metal comprising and is dispersed in said oil base, said composition exhibits a stability of less than about 1 to about 5% decomposition of the PS after a storage period of at least 6 months.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

DeFerra et al. is directed to a process for the purification of phosphatidylserine. DeFerra et al. teach a process for the purification of phosphatidylserines of formula I. It is taught that the importance of compounds of formula I is various particularly in the preparation of pharmaceutical composition for the therapy of involutive cerebral syndromes such as vascular pathologies on atheroschlerotic base and/or senile decline; for the preparation of liposomial formulations and dietetic compositions (paragraph 0003). The invention increases the purity of phosphatidylserine obtained from Epikuron 200. The further purified PS can be obtained by crystallization in the form of the

calcium salt (paragraph 0008). Examples 1-3 exemplify preparing a purified phosphatidylserine as the calcium salt from various lecithin sources.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

While DeFerra et al. teach that phosphatidyl serine are important in the preparation of pharmaceutical composition for the therapy of involutive cerebral syndromes including those associated with senile decline, DeFerra et al. do not explicitly teach incorporating the phosphatidyl serine in a pharmaceutical composition. However, this deficiency is cured by Jorissen et al.

Douglas Laboratories is directed to the product data sheet for a dietary supplement. The supplement is a softgel which contains a mixture of phospholipids and fatty acids. It is taught that the total phospholipids content is 500 mg wherein 100 mg is phosphatidyl serine, 45 mg is phosphatidylcholine, 10 mg is phosphatidyl ethanolamine, 5 mg is phosphatidylinositol and 360 mg is fatty acids. Other ingredients taught include medium chain triglycerides and soy bean oil (page 1 formula). It is taught the supplement is for individuals who wish to support the body's nervous system and brain function (page 1 indications). It is taught that one to three capsules are taken daily (page 1, suggested use).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of DeFerra et al. and Douglas Laboratories and utilize the purified phosphatidylserine in the pharmaceutical composition of Douglas

Laboratories. One of ordinary skill in the art would have been motivated to utilize the phosphatidylserine of DeFerra et al. in the pharmaceutical composition of Douglas Laboratories as DeFerra et al. teach that the phosphatidyl serine is important in the preparation of pharmaceutical compositions. Therefore, it would have been obvious to utilize purified phosphatidyl serine in known phosphatidyl serine pharmaceutical compositions.

Regarding the claimed storage stability, DeFerra et al. is silent. However, DeFerra et al. teach utilizing the instantly claimed divalent salt of phosphatidyl serine. Since known pharmaceutical preparations utilize medium chain triglycerides for diluting phosphatidyl serine, their use is obvious. Therefore, based on the teaching of DeFerra et al. that the phosphatidyl serine utilized is the divalent salt and is a purer form of phosphatidylserine, there is a reasonable expectation that the storage stability would be the same as instantly claimed. Because the PTO has no means to conduct analytical experiments and based on the substantially similar product components, the burden of proof is shifted to the Applicant to show that the functional limitation is not possessed by the prior art.

Regarding claim 21, since the soft gel capsules would be consumed by patients, the soft gel capsule encapsulating the phosphatidyl serine would read on a food article.

Regarding claims 2 and 55-57, the instant claim language recites and/or sterol or sterol esters. Therefore, one interpretation of the claims (via the "or" claim language) is that only one of the additional agents need to be present. The claims are rejected over this interpretation. Claims 55-57 recite an additional biofunctional ingredient. A

biofunctional agent is listed is phospholipids. Since Douglas Laboratories teach three additional phospholipids in the supplement, these not only read on the "or" claim language for the further including but also read on the additional biofunctional ingredient.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFerra et al. in view of Douglas Laboratories and in further view of Geiss (US PGPUB No. 20040120985).

Applicant Claims

The instant application claims a method of enhancing cognitive performance and learning ability in a subject, the method comprising administering to said subject an effective amount of the phosphatidyl composition stated above.

The instant application claims a method of improving age-related memory loss in a subject, the method comprising administering to said subject an effective amount of the phosphatidyl composition stated above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teaching of DeFerra et al. and Douglas Laboratories is set forth above. Specifically, DeFerra et al. teach a purified phosphatidyl serine calcium salt. It is taught phosphatidyl serine is important in the preparation of pharmaceutical composition for the therapy of involutive cerebral syndromes including those associated with senile decline. Douglas Laboratories teach that phosphatidyl serine soft gels are useful for individuals who wish to support brain function.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

While DeFerra et al. and Douglas Laboratories teach that phosphatidyl serine has use in supporting brain function, they do not teach utilizing phosphatidyl serine in the claimed method. However, this deficiency is cured by Geiss.

Geiss teaches that based on animal experimental studies the following statements can be considered confirmed facts. The administration of phosphatidyl serine protects against neuron atrophy, normalizes the cholesterol/phospholipids ratio in the aging brain, etc. (paragraph 0039). It is taught that neurophysiological test methods have been able to demonstrate the increase in cognitive function capacity in subjects between 40 and 80 years (paragraph 0041). This increase in cognitive function capacity includes demonstration of the increase in attentiveness and concentration and increase in memory and learning capacity (paragraphs 0043 and 0046).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of DeFerra et al., Douglas Laboratories and

Geiss and utilize the phosphatidyl serine supplement in a method of enhancing cognitive performance and learning ability as well as improving age-related memory loss. One of ordinary skill in the art would have been motivated to use the supplements in these methods as DeFerra e al. and Douglas laboratories recognized the use of phosphatidyl serine in brain support and Geiss teach that phosphatidyl serine has been demonstrated to increase cognitive functional capacity which includes improving learning and memory.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 3-5, 18 and 42-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 12/215080 (US 20090074857) is **withdrawn** in light of Applicants' amendments filed on December 18 2009.

The provisional rejection of claims 1, 3-5, 18 and 42-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-36 of copending Application No. 11872258 (US 20080085319) is **withdrawn** in light of the abandonment of '258 on 1/22/10.

The provisional rejection of claims 1, 3-5, 18 and 42-44 on the ground of non statutory obviousness-type double patenting as being unpatentble over claims 26-37 of copending Application No. 11/872440 (US 20080085320) is **withdrawn** in light of Applicants' amendments filed on December 18 2009.

The provisional rejection of claims 1, 3-5, 18 and 42-44 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 57-63, 70-75 and 77-79 of copending Application No. 11912925 (US 20090011075) is **withdrawn** in light of Applicants' amendments filed on December 18 2009.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616